REMARKS

The claims in the application are 21-27, 29-32, 34-39 and Claims 49-51 added by the present amendment.

Favorable reconsideration of the application as amended is respectfully requested.

Claims 21-25, 29, 34 and 36 have been amended to eliminate the rejections under 35 U.S.C. §112, second paragraph.

More particularly, the recitation deleted from Claim 25 has been introduced in new Claim 50. Molecular weights, based upon atomic weights, do not have units so Claims 21 and 31 constitute definitive recitation in this regard. Concerning the rejection of claims 21-27, 29, 30 and 36 under 35 U.S.C. §112, second paragraph and Claims 21-27 under 35 U.S.C. §101 raised on pages 6-7 of the Office Action, it is respectfully pointed out these claims are directed to a preparation and not a process, so it is unnecessary to recite specific processing steps in these claims. Moreover, use of the term "effective amount" is well-accepted definitive recitation in claim language (please see M.P.E.P. §2173.05(c) III.). In any event, the claims have been amended to recite the preparation is available in dosage form, there clearly being adequate support throughout the present application for this recitation.

Claims 21-27, 29-32 and 34-39 have been rejected under 35 U.S.C. §112, first paragraph on page 7 of the Office Action, on the grounds there is no support for the molecular weight range of 20,000 to 100,000 in the examples which just show molecular weights of either 20,000 or 100,000. It is respectfully submitted the two preparation examples in the present application provide

adequate support for this range. Furthermore, Claims 21 and 31 have been amended to recite the inventive ingredient is present at a molecular weight of at least 20,000, there clearly being adequate support in the examples.

Additionally, Claims 21 and 31 have been amended to recite the sericin is extracted as a single protein from silk worm cocoons or raw silk at a purity of 90% or higher; support for this recitation is found, e.g., at page 6, line 1 - page 7, line 2 and in preparation Examples 1 and 2 on page 9 the present application. It is respectfully submitted this recitation concerns the actual physical and chemical state of the sericin and is not a mere processing limitation. The sericin is the sole protein extracted from silk which is used in the present invention, with other proteins such as fibroin not being used.

Accordingly, the only outstanding issue is the art rejection of the claims. More particularly, Claims 21-27, 29-32 and 34-39 have been rejected under 35 U.S.C. §102(b) as being anticipated by JP 1-256351 on pages 2-4 of the Office Action and under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,165,982 to Yamada et al on pages 4-5 of the Office Action. In any event, it is respectfully submitted all claims pending herein define over the applied art, for the following reasons.

Concerning the arguments against JP1-256351 raised in the previous amendment, the Examiner requests on page 3 of the Office Action submission of a Declaration under 37 C.F.R. §1.132 from one having firsthand knowledge and substantiating the compositions of the claimed invention and the cited reference

do not possess the same material, structure and functional characteristics. Accordingly, such a Declaration executed by joint inventor Masahiro Sasaki is submitted herewith.

It is stated in paragraph 3 of the enclosed Declaration, the present invention, provides an improved preparation for preventing colon cancer (and providing other gastrointestinal benefits) by administering an effective amount of water-soluble sericin or hydrolyzed product thereof. These benefits provided by the claimed invention have been explicitly documented in the demonstrative and comparative testing set forth in Test Examples 1-7 on pages 9-20 of the present application and illustrated, e.g., in accompanying Figs. 1-4.

In particular, the inventive functional oral preparation contains sericin which has been extracted as a single protein from silk worm cocoons or raw silk with a purity of 90% or higher, or hydrolyzed product having an average molecular weight range of at least 20,000, in an effective amount to prevent colon cancer in dosage form (paragraph 4). JP 1-256351 fails to suggest to Mr. Sasaki the chemical or physical structure of the sericin used in the claimed oral preparation for the following reasons.

Independent Claims 21 and 31 recite, among other features, the sericin and/or hydrolyzed product ingredient is present in an average molecular weight of at least 20,000.

Mr. Sasaki has translated an excerpt from the preparation part of the Examples in JP 1-256351, namely Example 1:

"Example 1

Waste silkworm cocoons were subjected to a treatment in a solution of sodium carbonate of 0.5% at a bath ratio of 50 times and a bath temperature of 90 °C for 30 minutes twice. Then, the fibroin containing product was dissolved in an aqueous solution of calcium chloride and ethanol, thereafter suction-filtered and poured into a cellulose tube to dialyze to obtain an aqueous fibroin solution having a concentration of 4%. Then, both aqueous solutions were mixed in equal amounts to obtain an aqueous mixture solution which was added into commercially available 100% orange juice and then the pH was adjusted to 4 by using citric acid to obtain a food in which fibroin and sericin were gelled."

In the other Examples, the preparation of the silk proteins is not shown at all and the same silk protein prepared in Example 1 is used. Mr. Sasaki then explicitly states, in paragraph 7 of his Declaration, the preparation conditions (i.e., 0.5% Na_2CO_3, 90 °C, 30 minutes x2) provide a sericin having an average molecular weight of only about 3,000.

Furthermore, Mr. Sasaki states while the sericin used in JP1-256351 might be "water-soluble" just after being derived from silkworm cocoons or raw silk, nevertheless it is essential to JP1-256351 that such sericin gel, even by merely being left to stand without any further treatment. More specifically, it has been explicitly ascertained by Mr. Sasaki that JP1-256351 explicitly discloses:

> An aqueous fibroin solution and aqueous sericin solution are both gelled even by leaving it as stands [emphasis added]

In contrast, the sericin and/or hydrolyzed product used in the present invention cannot be gelled as an aqueous solution in the absence of gelling agent, with the aqueous solution thus being maintained upon standing, unlike the sericin in JP1-256351. Thus the chemical or physical structure of the sericin used in the present invention is different from the sericin used in the applied reference.

Accordingly, JP 1-256351 neither discloses nor suggests to Mr. Sasaki preparation of the inventive composition attaining the advantageous improvements documented in the present application. Therefore, the claimed composition is clearly different from and not at all anticipated by JP1-256351.

Concerning Yamada et al, it is respectfully pointed out this reference fails to disclose an effective amount of sericin and/or hydrolyzed product to either prevent colon cancer (independent Claims 21 and 31) or any of the effective amounts enumerated, e.g., in the various dependent claims. In this regard, the claims have been amended to add "in a dosage form" for clarifying the term "effective amount" for preventing colon cancer.

As presented in the previous response, the term "effective amount" has long been accepted as both definite in a claim and capable of defining over the prior art: In re Mattison, 509 F.2d 563, 184 USPQ 484 (CCPA 1975); In re Halleck, 422 F.2d 911, 164 USPQ 647 (CCPA 1970); Ex parte Skuballa, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989); and Ex part Balzarini, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991). All "effective amounts" of the invention recited in the claims has been amply documented by the evidence contained in the present application.

In this regard, it is respectfully pointed out neither JP1-256351 nor Yamada et al discloses or suggests using sericin having the claimed level of purity to attain the preventive benefits against colon cancer. It is also well-settled purer forms substances can most certainly impart patentability.

Accordingly, in view of the forgoing amendment, accompanying remarks and enclosed Declaration, it is respectfully submitted all claims pending in the present application are in condition for allowance. Please contact the undersigned attorney should there be any questions. A petition for an automatic two month extension of time for response under 37 C.F.R. §1.136(a) is enclosed in triplicate together with the requisite petition fee.

Early favorable action is earnestly solicited.

Respectfully submitted,

George M. Kaplan
Reg. No. 28,375
Attorney for Applicant(s)

DILWORTH & BARRESE, LLP
333 Earle Ovington Blvd.
Uniondale, New York 11553
Phone: 516-228-8484
Facsimile: 516-228-8516

GMK/JWK